SECTION 5 - SUMMARY

OCT 23 2007

Scholten Surgical Instruments, Inc.
170 Commerce St. #101
Lodi, CA 95240 - USA

510k SUMMARY

510K Number: K072051

Submitter: Jim Van Andel, Chief Operations Officer

Scholten Surgical Instruments, Inc.

170 Commerce St. #101

Lodi, CA 95240 – USA

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Establishment Registration Number: 2936330

Date Prepared: July 20, 2007

Trade Name: Novatome™ Endomyocardial Biopsy Forceps

Common Name: Endomyocardial Biopsy Forceps, Bioptome

Classification Name: device, biopsy, endomyocardial (21 CFR 870.4075)

Predicate Devices:

The Scholten Bioptome by Scholten Surgical Instruments Inc. and the Ultra-CBX™ by Medcanica

Device Description:

The Scholten Surgical Instruments, Inc. Novatome is a manually operated hand held surgical instrument designed to remove biopsy samples from the right or left ventricle of the Human Heart via percutaneous venous or arterial access. Specifically via the internal Jugular or subclavian veins or the femoral artery.

Device Design:

The device consists of three main parts. The cutting jaws, a polymer coated flexible shaft, and an actuating handle. At the distal end of the forceps is a pair of jaws used to obtain the heart tissue samples. At the proximal end of the forceps is the actuation handle used to activate the jaws and steer the device

The device cutting jaws are single action in that one of the jaws is fixed and is attached to the end of the flexible shaft and the other jaw is movable and is attached to a link that is welded to the end of the actuation wire. The single moving jaw, the distance the jaws open, as well as the orientation of the jaw work in combination to control the amount of tissue obtained. These design characteristics are the identical to the Scholten Surgical Instruments, Inc. Scholten Bioptome.

The Novatome's actuation handle is made of an advanced high-performance polymer. The jaws, actuation wire, and other mechanical parts are made of stainless steel. The flexible shaft sheath material is Fluoropolymer tubing.

Device physical properties:

The Novatome™ will be available in 9,8,7, and 6 French cutting jaw sizes, with flexible shaft lengths of 50, 70, and 100cm lengths. These lengths are standard in the industry for endomyocardial biopsy devices.

Intended Use (Indications for use):

The Scholten Novatome™ is a surgical device used to perform endomyocardial biopsies.

Comparison of technological characteristics:

The Novatome™ is designed with the same characteristics as the predicate devices. It, like the others, is designed for endomyocardial biopsy. The Scholten Surgical Instruments Novatome™ is a single use device as is the Ultra-CBX ™ by Medicanica. The Scholten Surgical Instruments Bioptome is reusable.

Additionally, the Novatome™ and the Scholten Bioptome both share a hemostat type finger ring actuating handle that is at a right angle to the flexible shaft. The Novatome™ actuating handle is constructed of a strong light weight,

material that is injection molded yielding dimensionally consistent components as opposed to the Scholten Bioptome's stainless steel actuating handle constructed from forged components that are hand assembled and hand finished. The Bioptome and the Novatome actuation handles share virtually identical physical geometry. The Ultra-CBX ™ by Medicanica uses a 3 pull-ring style actuating handle.

Both the Scholten Bioptome and the Novatome™ share the same cutting head design as well as the same flexible shaft construction

One difference between the Novatome™ and the Scholten Bioptome is the device packaging. The Scholten Bioptome is sold non-sterile and is sterilized by autoclaving at the end user facility. The Novatome and the predicate Ultra-CBX ™ by Medicanica are pre-packaged and sterilized

Non clinical test performed for determination of substantial equivalence are as follows:

Performance tests were conducted in several areas including, dimensional, tensile, simulated biopsy yield, cutting jaw force tests.

Discussion of Clinical test Performed:

Clinical studies were not conducted on the Novatome forceps.

Conclusion:

The Novatome™ was designed utilizing design control methods and is safe and effective for the application for which it is intended. Based on the comparison of the intended use, the design of the predicate devices, and the results of all testing performed, the proposed Novatome™ shows substantially equivalence to the predicate devices.,

End of Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2007

Scholten Surgical Instruments, Inc.
c/o Jim Van Andel
Chief Operations Officer
170 Commerce St. #101
Lodi, CA 95240

Re: K072051
Novatome™ Endomyocardial Biopsy Forceps
Regulation Number: 21 CFR 870.4075
Regulation Name: Endomyocardial Biopsy Device
Regulatory Class: Class II (two)
Product Code: DWZ
Dated: July 20, 2007
Received: July 31, 2007

Dear Mr. Van Andel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATION FOR USE

Indications for Use

510(k) Number (if known): K072051

Device Name: Novatome™ Endomyocardial Biopsy Forceps

Indications for Use: The Scholten Novatome™ is a surgical device used to perform endomyocardial biopsies.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

Prescription Use
(Per 21 CFR 801.109)

Indications for Use Page 1 of 1

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